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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/675,938	09/29/2000	James E. McShane	FC0807Q1	1065

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SCHERING-PLOUGH CORPORATION
PATENT DEPARTMENT (K-6-1, 1990)
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EXAMINER

SHARAREH, SHAHNAM J

ART UNIT PAPER NUMBER

1617

DATE MAILED: 06/03/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/675,938

Applicant(s)

MC SHANE, JAMES E.

Examiner

Shahnam Sharareh

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO MONTH for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 3/5/2002, 09/29/00.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-20 is/are pending in the application.
- 4a) Of the above claim(s) 11-20 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-10 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claim(s) 11-20 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 2.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

DETAILED ACTION

Election/Restrictions

1. Applicant's election without traverse of Group I in Paper No. 5 is acknowledged.
Claims 11-20 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim. Election was made **without** traverse in Paper No. 5.
2. This application contains claims 11-20 drawn to an invention nonelected with traverse in Paper No. 5. A complete reply to the final rejection must include cancellation of nonelected claims or other appropriate action (37 CFR 1.144) See MPEP § 821.01.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

3. Claim 8-10 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.
4. The phrase "a more pleasant odor" in claim 8 is a relative term, which renders the claim indefinite. The phrase "a more pleasant odor" is not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably appraised of the scope of the invention. Furthermore, such a measurement is not an art recognized standard, rather, it is a subjective and variable measurement among general population. Thus, claim 8 and all dependent claims thereof are rejected

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

5. Claims 1-10 are rejected under 35 U.S.C. 102(b) as being anticipated by Nakane et al US Patent 5,122,418.

The instant claims are directed to a pressurized aerosol comprising (a) micronized zinc oxide, (b) a propellant, (c) a solvent wherein the amount of micronized zinc oxide ranges from about 0.5 to about 15% by weight.

Nakane et al disclose micronized zinc oxide products comprising a thickening agent such as silica or silicates, a fragrance such as absolute Jasmine or lavender oil (see abstract, col 5, lines 36-65; col 6, lines 1-11; col 9, lines 13-31; col 10, lines 19-22, 45-51; col 9, lines 40-50; col 12, lines 9-12, lines 23-25; col 13, lines 29-30; examples 30-40). The amount of zinc oxide used in Nakane's compositions falls within the same range as instantly claimed (see col 10, lines 58-61; examples 35-38). Nakane's composition also comprise a propellant as an aerosol deodorant spray and can be used for spraying on the body, therefore, they meet the limitations of the instant usage (example 31, 35-36). Nakane's spherical powder have the average particle size of 1 to 100 microns (see col 5, lines 38-41) wherein the zinc oxide particles have an average size of 0.01-10 microns which is equal to 10 – 1000nm (col 10, lines 19-22. Accordingly,

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the preferred zinc oxide particles of Nakane anticipate the instantly claimed particle sizes. Thus, Nakane's compositions anticipate the limitations of the instant claims.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
 2. Ascertaining the differences between the prior art and the claims at issue.
 3. Resolving the level of ordinary skill in the pertinent art.
 4. Considering objective evidence present in the application indicating obviousness or nonobviousness.
6. Claims 1-10 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lajoie US Patent 5,466,470 in view of Lisboa et al US Patent 5,679,324.

Lajoie discloses co micronized bicarbonate salts and zinc oxide in particles sizes of 0.01 – 1.0 micron (see abstract, col 2, lines 61). Lajoie further teaches the use of zinc oxide powders in his formulations in the same amount and particles sizes as instantly claimed (see col 5, lines 1-13; col 8, lines 4-25). Lajoie also teaches the use of Thickeners, surfactants and fragrances in his compositions (examples 3-4). Lajoie does not employ teach an aerosol formulation that contains a propellant for expelling the content of the formulation.

Lisboa et al teaches propellant containing topical cosmetic or therapeutic compositions (see abstract). Lisboa suggests that the use of aerosol compositions gaining wide appeal among both men and women as they are easy to use (see col 1, lines 17-40). Lisboa further teaches that the use of propellants in preparing an aerosol formulation containing various cosmetically suitable ingredients is conventional. In fact, Lisboa suggests the addition of various suitable ingredients such as surfactants, thickeners, moisturizers, coolants, emollients and even sunscreen agents of choice such as zinc oxide for their known therapeutic or cosmetic use (see abstract; col 2, lines 40-67; col 3, lines 55-67; col 6, lines 14-67; col 8, lines 11-20).

Accordingly, it would have been obvious to one of ordinary skill in the art at the time of invention to add a propellant, such as those taught by Lisboa, to the compositions of Lajoie and formulate an aerosol topical delivery system of Lajoie's compositions, because one of ordinary skill in the art would have had a reasonable expectation to succeed in formulating aerosolized formulations that are easy to use and are more appealing to the general consumers.

Conclusion

7. No claims are allowed. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Shahnam Sharareh, PharmD whose telephone number is 703-306-5400. The examiner can normally be reached on 8:30 am - 6:00 pm.

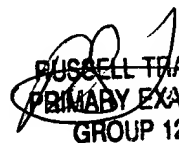
If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Minna Moezie, JD can be reached on 703-308-4612. The fax phone

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numbers for the organization where this application or proceeding is assigned are 703-308-4556 for regular communications and 703-308-4556 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-1123.

ss
May 27, 2002


RUSSELL TRAVERS
PRIMARY EXAMINER
GROUP 1200